-- REMARKS--

The Applicant has carefully reviewed the statements the Examiner presented in the Non-Final Rejection (mailed May 31, 2007) which rejected all of the claims of the application and has also carefully reviewed the cited references upon which the rejections are based. The Applicant has amended claims and incorporated suggested changes by the Examiner and traversed the rejections. The Applicant respectfully requests reconsideration and re-examination of the claims of the application.

Response to Interview Summary for June 26, 2007 Examiner Interview

The Examiner prepared interview summary for the June 26, 2007 interview has been carefully studied by the Applicant. The Applicant has the following comments to add to the Examiner prepared Interview Summary.

Regarding the Applicant's assertion that Morris was inapplicable, the Applicant made further clarification of Morris than is recorded in the interview summary. The Applicant explained in technical detail why the pressure transducer in the cuff used by Morris does not measure the pressure within the brachial artery of the manikin but simply measures the pressure within the cuff which is inflated manually. The Applicant described how, by the teaching of Morris, the cuff could be positioned anywhere not even attached to the manikin (so long as it was electrically connected to the comparator) and inflated and still cause the pulsations within the system of Morris to cease thereby further proving that the pressure transducer in the cuff could not possibly measure the pressure inside the simulated artery. The Applicant conveyed that the pressure in the simulated blood vessels of Morris is never measured by a pressure transducer, and that it is only in an external cuff that a pressure is measured which is not physically related to the pressure inside the simulated vessels. The Applicant expressed concern that the Examiners did not fully understand the technical details of the teaching of Morris in how the cuff/vessel system worked. Examiner Gishnock replied he would further study the details. Nevertheless, as a way of compromise to further the prosecution, the Applicant suggested that he include the feature of a pressure sensor in contact with the pressurized fluid in some of the claims.

The Applicant disagrees that he explained that an incompressible member is required inside of the hollow bulb as the Examiners' summary appears to assert. The Applicant simply stated that an incompressible member can help some persons such as the elderly with a generally weaker grip strength to better use the invention since it provides a bulb compression goal to achieve while gripping the bulb. It is noted that neither of the fully functional prototypes on display to the Examiners during the interview had such an incompressible member in place. The Applicant made the Examiners aware of this when he was asked about the incompressible member function. The Applicant did not indicate that such a member was required for the invention to operate in all embodiments of the invention.

Regarding the differences in a bulb versus a smaller diameter tube, the Examiners admitted that the Applicant does teach in his specification the advantage of using a larger diameter vessel compared to a smaller diameter tube to provide amplified tactile feedback and therefore, the difference between a bulb and tube is not simply a design choice.

When the Examiners mentioned that another search will need to be performed, the Applicant expressed concern that at least five prior art searches had been performed in this case already through a number of different examiners.

Claim Objected to under 37 CFR 1.75(c)

Claim 6 is objected to by the Examiner since the limitation of Claim 6 was included in Claim 1 as amended. The Applicant agrees and has canceled Claim 6 in this Amendment G.

Claims Rejections under 35USC §102(e):

Claims 1, 2, 4, 6-8, 10, 14-16, 29, 30, 35, 39, 40, 46, 47, and 57 are rejected by the Examiner under 35USC §102(e) as being anticipated by Morris et al (US 7,021,940) hereafter known as Morris. Claims 1, 29, 39, and 57 are the independent claims within this group.

Claims 1, 29, and 39 were amended to be placed in a form containing more structural than functional language as suggested by the Examiner and were further amended to include the feature that a pressure sensor in contact with the pressurized fluid electronically senses pressure levels within the pressure vessel (chamber in Claim 39) and provides data feedback to the electronic control unit. Support for this amendment is found in the sixth sentence of paragraph 0012 of the Applicant's specification. The Applicant submits that Morris does not teach of a pressure sensor in contact with the pressurized fluid simulating blood flow in his disclosure. Only the pressure inside a standard blood pressure cuff is measured with a transducer when a blood pressure measuring training function of the Morris invention is used. Therefore, the Morris invention is quite unlike the Applicant's invention in structure and function and does not teach every limitation of the Claims 1, 29, and 39 as amended. Therefore, for at least this reason, the Applicant respectfully requests that the 102(e) rejections of Claims 1, 29, and 39 be withdrawn and the claims allowed.

Claim 57 was amended to include the feature of "an element to generate the pressurized fluid outside of the bulb whereby pressure levels of the pressurized fluid are pneumatically conveyed to inside of the bulb through a conduit of smaller diameter than the bulb thereby resulting in force amplification within the bulb compared to within the conduit". Support for this amendment is found in paragraph 0016 of the Applicant's invention where the Applicant explains the advantages of a bulb over a small diameter tube is force amplification in the bulb. This limitation distinguishes between a small diameter tube (2-3mm diameter as taught by Morris) and a relatively large diameter elastomeric bulb where the walls of the larger diameter bulb experience greater forces than the walls of a smaller diameter tube with both experiencing the same pressure level. A human gripping a bulb has far greater tactile fidelity in distinguishing between internal pressure level differences than a human attempting to receive tactile feedback from a small diameter tube such as the 2-3mm tube as taught by Morris. It is well known that even relative human blood pressure levels cannot be determined by feeling of the blood vessels through the skin. A relatively small diameter tube is fluid dynamically much different than a larger diameter bulb with respect to forces experienced by the respective vessel walls if both vessels experience the same pressure. Also, Morris teaches that all of his blood vessel simulations consist of a small diameter silicone tube, and only the presence of a simulated pulse is felt within the tube not the blood pressure levels. The Applicant submits that Morris does not teach of the use of an elastomeric bulb and said bulb has been shown to be different than a relatively smaller diameter tube. The Applicant teaches the advantage of a hollow bulb over a smaller diameter tube with respect to force amplification in the bulb, therefore, the selection of a bulb over a smaller diameter tube as the tactile feedback vessel is not simply a design choice. Since Morris does not teach all of the limitations of amended Claim 57, the Applicant submits that the 102(e) rejection is improper and requests that the rejection be withdrawn and the claim allowed.

Claim 6 is canceled.

Dependent Claims 2, 4, 7-8, 10, and 14-16 depend on Claim 1 and therefore have all of the limitations of Claim 1. Claim 1 has been traversed as it shown that Morris does not teach each element of Claim 1. For at least this reason, the Applicant submits that the 102(e) rejections are improper and Claims 2, 4, 7-8, 10, and 14-16 are in condition for allowance. Applicant requests that the rejections be withdrawn and the claims allowed.

Dependent Claims 30 and 35 depend on Claim 29 and therefore have all of the limitations of Claim 29. Claim 29 has been traversed as it shown that Morris does not teach each element of Claim 29. For at least this reason, the Applicant submits that the 102(e) rejections are improper and Claims 30 and 35 are in condition for allowance. Applicant requests that the rejections be withdrawn and the claims allowed.

Dependent Claim 40 depends on Claim 39 and therefore has all of the limitations of Claim 39. Claim 39 has been traversed as it shown that Morris does not teach each element of Claim 39. For at least this reason, the Applicant submits the 102(e) rejection is improper and that Claim 40 is in condition for allowance. Applicant requests that the rejection be withdrawn and the claim allowed.

Dependent Claims 46 and 47 depend directly and indirectly, respectively, on Claim 29 and therefore have all of the limitations of Claim 29. Claim 29 has been traversed as it shown that Morris does not teach each element of Claim 29. For at least this reason, the Applicant submits the 102(e) rejections are improper and that Claims 46 and 47 are in condition for allowance. Applicant requests that the rejections be withdrawn and the claims allowed.

Claims 19, 20, 23, 26, 28, 36, 37, 44, 45, 50-53 & 56 are rejected by the Examiner under 35USC §103(a) as being anticipated by Morris et al (US 7,021,940) hereafter known as Morris. Claims 19 and 36 are the independent claims within this group. The Examiner describes Morris as exhibiting all of the elements independent Claims 19 and 36.

The Applicant has amended Claims 19 and 36 to include the feature of the presence of simulated diastolic and systolic blood pressure levels. Support for this amendment is found at least in paragraph 0012 of the specification.

The Applicant points to Column 4, lines 17-25 of Morris where the Examiner alleges that Morris teaches "simulating cyclic normal and abnormal conditions within various fluids carrying body cavities, such as blood flow within a blood vessel". Below is the excerpt from Morris Column 4, lines 17-25:

> *"The system described above can be used to simulate fluid flow conditions within various fluid carrying body cavities, including in particular respiratory air flow within a pair of lungs or blood flow within a blood vessel. The system may also be utilised to simulate other conditions such as fluid pressure acting on the skull of a patient. A series of systems as described can be utilised to simulate various conditions within various fluid carrying body cavities of a single manikin."*

The Applicant respectfully requests that the Examiner specifically point out where in the above excerpt that Morris explicitly teaches or implies that "the periodic pressure amplitudes comprising at least one normal, human blood pressure amplitude cycle and at least one abnormal, human blood pressure amplitude cycle in the pressure vessel" which is a feature of Claim 19. The Applicant submits that Morris has merely made very general, sweeping statements without specificity to the scope of his invention except that it relates to lungs, blood vessels and skulls within this cited excerpt. For example, Morris uses the highly indefinite word "various" three times and indefinite words "other conditions" and "such as" within this short excerpt to which the Examiner points to for rejecting Claim 19. The Applicant respectfully submits that the use of this teaching of Morris to be equivalent to the above limitation of Claim 19 is based on highly indefinite language and extrapolation of Morris' teaching by the Examiner and is therefore improper to reject Claim 19.

Further, regarding Claims 19 and 36, the Examiner admits that Morris does not teach where an electronic switch toggles between simulating the normal and abnormal blood pressure amplitude cycles. However, the Examiner goes on to state since Morris teaches of a feature of his system whereby a user can simulate a pneumothorax of one lung by the operation of a control to stop simulated respiration into one lung, that it would be obvious to include a switch to toggle between normal and abnormal blood pressure amplitude levels and pulse rates. The Applicant most respectfully submits that the Examiner has made an extreme extrapolation of Morris' teaching in claiming that toggling between the existence and non-existence of a simulated pneumothorax renders obvious toggling between normal and abnormal simulated blood pressure levels. A respiratory anomaly and a cardiovascular anomaly are very different phenomena whereby Morris teaches of a binary condition of one or two lungs where the Applicant teaches of a nearly infinite possibility of switching between normal blood pressure and any number of abnormal blood pressure levels. Most importantly, the addition of a switch to toggle between normal and abnormal blood pressure in Morris as the Examiner suggests to meet the Applicant's claims could not be expected to meet with reasonable success since there is no teaching of any mechanism within the manikin system to provide pressure control on the fly to the define when normal and abnormal blood pressure levels are simulated at a human cardiac pulse rate. Only when a cuff containing a pressure sensor is inflated such that the cuff pressure transducer output compares to the blood pressure dial 24 output is there any control over the pulsation of the simulated flow of blood in the brachial artery in Morris. This control is simply binary in that 1) when the cuff pressure is high enough drive the cuff pressure transducer output to equal the output from the blood pressure dial 24, solenoid 403 closes and no simulated blood flows in the simulated brachial artery and 2) when the cuff pressure is released by a standard method of using a blood pressure cuff (bleeding air from the inflation bulb), the solenoid 403 begins to cycle again causing pressure pulsations again in the artery. There is no pulsation pressure amplitude control taught in Morris' cardiac simulation system other than "pulse or no pulse" within the pressure vessel; therefore, there cannot be any normal or abnormal human blood pressure cycle simulation at a frequency equal to a human cardiac pulse rate. See Columns 7 and 8 lines 40-67 and 1-3, respectively. Note that the way Morris' system is designed, the cuff need not be inflated on the manikin arm and the system would function the same way, the cuff just needs to be inflated *somewhere* to increase its internal pressure. Wrapping the cuff around the manikin arm is only part of a training exercise. It is not the force of the cuff on the simulated blood pressure vessel which is intended to stop the flow of simulated blood as it does in an actual human blood pressure measurement, but rather it is the cuff pressure transducer output equaling the blood pressure dial 24 output through a comparator 23 that closes the solenoid 403 (Column 7 lines 55-60) . Morris discloses here that the action of closing solenoid 403 has the same *effect* of stopping the flow of blood when the systolic pressure is reached in the cuff, but it is clearly a *different action* in that no blood vessel pressure is *actually* measured since it is not possible to do so with the Morris apparatus as taught. Therefore, it should be clear that no simulated blood pressure in the vessel is actually measured in Morris' disclosure and therefore normal and abnormal simulated blood pressure cycles at a frequency of a human cardiac pulse rate cannot be simulated.

Even further, with the flow of simulated blood stopped with the closing of solenoid 403 at the "blood pressure dial 24"defined systolic pressure experienced in the cuff (and NOT in the vessel) as taught by Morris, there could not be a tactile feel by a human of even a pulse rate in the pressure vessel much less a blood pressure level the way the Morris system is designed.

Therefore, even the inventive step of adding a switch to toggle back and forth between normal and abnormal blood pressure levels in Morris as the Examiner suggests would not possibly provide contrasting levels of blood pressure cycle-induced forces that could be felt by a human in contact with a pressure vessel as is only taught in the Applicant's invention.

The Applicant submits for any and all of the numerous reasons above that Morris has not taught all of the elements of Claims 19 and 36, nor have the claims been rendered obvious since there could be no expected level of success (as is required to support a case of prima facie obviousness) by the Examiner's suggestion of adding a toggle switch to the cardiac simulation of Morris. Therefore, the 103(a) rejections of amended Claims 19 and 36 are improper for the reasons described above, and the Applicant requests that the rejections be withdrawn. Allowance of Claims 19 and 36 are hereby requested.

Dependent Claims 20, 23, 26, 28, 44, and 45 depend directly or indirectly on Claim 19 and therefore have all of the limitations of Claim 19. Claim 19 has been traversed as it has been shown that Morris does not teach every element of the claim. For at least this reason, the Applicant submits that Claims 20, 23, 26, 28, 44, and 45 are in condition for allowance and requests that Claims be allowed.

Claim 52 is canceled since the feature of this claim was incorporated into Claim 36 in the previous Amendment.

Dependent Claims 37 and 56 depend on Claim 36 and therefore have all of the limitations of Claim 36. Claim 36 has been traversed as it has been shown that Morris does not teach every element of the claim. For at least this reason, the Applicant submits that Claims 37 and 56 are in condition for allowance and requests that the rejections be withdrawn and the claims allowed.

Dependent Claim 50 depends on Claim 1 and therefore has all of the limitations of Claim 1. Claim 1 has been traversed as it has been shown that Morris does not teach every element of the claim. For at least this reason, the Applicant submits that Claim 50 is condition for allowance and requests that the rejection be withdrawn and the claims allowed.

Dependent Claim 51 depends on Claim 29 and therefore has all of the limitations of Claim 29. Claim 29 has been traversed as it has been shown that Morris does not teach every element of the claim. For at least this reason, the Applicant submits that Claim 51 is condition for allowance and requests that the rejection be withdrawn and the claims allowed.

Dependent Claim 53 depends on Claim 39 and therefore has all of the limitations of Claim 39. Claim 39 has been traversed as it has been shown that Morris does not teach every element of the claim. For at least this reason, the Applicant submits that Claim 53 is condition for allowance and requests that the rejection be withdrawn and the claims allowed.

Claims 3, 21, 22, 31, 33, 38, & 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris in view of Futcher (US 5,722,413) hereinafter known as Futcher. Claims 3, 21, 22, 31, 33, 38, & 41 are all dependent claims depending upon their respective independent claims and therefore have the limitations of said respective independent claims which have all been traversed herein as it is shown that Morris does not teach every element of the independent claims. The Applicant submits that since not every element is taught by Morris in view of Futcher in Claims 3, 21, 22, 31, 33, 38, & 41 the 103(a) rejections are improper and these claims are now in condition for allowance. Applicant requests that the rejections be withdrawn and the claims allowed.

Claims 9, 13, 25, 27, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris in view of Tumey (US 5,9891,654) hereinafter know as Tumey. The Examiner cites column 8, lines 9-41 of Tumey as teaching an air cuff that is periodically inflated and deflated. The Applicant points to column 8, line 27 where Tumey teaches of a time period of about 120 seconds which occurs before the pressurized cuff is deflated. Therefore, the Applicant submits that Tumey clearly teaches away from cycling the pressure in a vessel at the rate of a human cardiac pulse rate. Claims 9, 13, 25, 27, 32, and 34 are all dependent claims depending upon their respective independent claims and therefore have the limitations of said respective independent claims which have all been traversed herein as it is shown that Morris does not teach every element of the independent claims. The Applicant submits that since not every element is taught by Morris in view of Tumey in Claims 9, 13, 25, 27, 32, and 34, a 103(a) rejection is improper. These claims are now in condition for allowance and the Applicant requests that the rejections be withdrawn and the claims allowed.

Claims 11 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris in view of claims 1 and 19 and in further view of Frazier (US 6,669,624) hereinafter known as Frazier. The Applicant submits that the Examiner has misunderstood the purpose of the incompressible, non-liquid member inside of the elastomeric hollow bulb serving as a tactile interface. This member is not included to aid in rapid cyclic inflation and deflation in the Applicant's invention as the Examiner suggests, but rather to provide a substrate for the user of the device to press the bulb walls against to maintain a consistent feel (a compression goal) and to reduce the tendency for the user to randomly squeeze the bulb during the blood pressure simulation (see paragraph 0013). As such, the combined teachings of Morris and Frazier would not be looked to by a skilled artisan to solve the problem that is solved by the Applicant in these claims. The combination of the references would also render Frazier unsatisfactory for its intended use since the bulb in Frazier is not intended to be compressed by a human hand and, in fact, is not possible to do so in its intended use inside the vascular system of a human. The Applicant submits that the references must be considered as what they teach as a whole and not simply as a tool box for which to build the Applicant's invention. Also, since these dependent claims have all of the limitations of the independent claims on which they depend and the combination of Morris and Frazier do not teach every element of the dependent claims 11 and 15, the Applicant submits, for this reason and those listed above, that Claims 11 and 55 are in condition for allowance and requests that the rejections be withdrawn and the claims allowed.

Claim 42 is rejected under 35USC §103(a) as being unpatentable over Baldwin (4,773,865) in view of Morris. The Applicant has amended Claim 42 to include the feature that the two bulbs are connected by a smaller diameter conduit such that the pressure-induced force is amplified in the bulbs compared to the conduit. Support for this amendment is found in paragraph 0016 in the Applicant's specification. The Examiner states that Baldwin teaches of a first elastomeric bulb to pressurize fluid and of a second elastomeric bulb (a simulated femoral artery 52' in a simulated leg) which is pneumatically connected to the first bulb through a bi-directional flow connection such that the pressure in the second bulb is controlled by the amount of compression in the first bulb; the second bulb providing a tactile interface to the human subject where the human subject physically senses the fluid pressure magnitudes internal to the second bulb by gripping the bulb with at least one hand. The Examiner then combines the teaching of Morris to add a visual indicator to the teaching of Baldwin in an attempt to arrive at the Applicant's invention. The Applicant respectfully submits that the tube to simulate a femoral artery 52' in Baldwin is very clearly buried deeply within the simulated leg 36 (see Fig. 6 of Baldwin) whereby it would not be physically possible for a human hand to grip this element as is a feature in Claim 42 of the Applicant's invention (similarly for arteries buried in the simulated neck). Also, just as important, the simulated femoral artery 52' of Baldwin (or other simulated arteries) is not a second elastomeric bulb. See Applicant's specification paragraph 0016 where it is taught that one function of an elastomeric bulb is to provide significant force amplification within the pressure vessel compared to the force exerted on the walls of relatively small diameter conduits. The Applicant teaches an advantage of an elastomeric bulb over a relatively small diameter tube (52' in Baldwin) which the Examiner improperly considered as an equivalent of an elastomeric bulb in rejecting Claim 42.

The Applicant would like to point out that in the Non-Final Rejection mailed May 31, 2007, the Examiner rebutted the previous arguments made by the Applicant that an elastomeric bulb is different from a small diameter tube. The Examiner stated that he used the teaching of Baldwin as well as the Applicant's teaching to conclude that "the pressure generated in a bulb with a larger surface area and conveyed to a bulb with a smaller surface area would amplify the force in the bulb with the smaller surface area, thus enabling the amplified pressure to be felt." The Applicant respectfully submits that the Examiner has misunderstood the physics regarding force amplification in connected fluid filled volumes of differing sizes. For two connected pressure vessels of different volume (large bulb versus a small bulb) each having equal pressure, then the larger volume vessel will experience the greater force over its entire surface since the pressure acts over a greater area. The force amplification comes from the pressure acting over a larger area to induce a larger force on the integrated surfaces of the larger bulb. Thus, the larger bulb will experience the force amplification, not the smaller bulb as the Examiner has concluded. The Applicant believes his teaching is clear in this regard in paragraph 0016 of the specification. The also Applicant believes that he has made clear that a relatively large diameter bulb is not the same as relatively small diameter tube connected to the bulb with respect to forces experienced by a human gripping the vessels. The Applicant teaches the advantage of a hollow bulb over a smaller diameter tube with respect to force amplification in the bulb, therefore, the selection of a bulb over a smaller diameter tube as the tactile feedback vessel is not simply a design choice.

Since every element of amended Claim 42 is not taught by a combination of Baldwin and Morris, the Applicant submits that the 35USC §103(a) rejection is improper and should be withdrawn. The Applicant requests that Claim 42 be allowed.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin in view of Morris in view of claim 42 and further in view of Frazier. The Applicant submits that the Examiner has misunderstood the purpose of the incompressible, non-liquid member inside of the elastomeric hollow bulb serving as a tactile interface. This member is not included to aid in rapid cyclic inflation and deflation in the Applicant's invention as the Examiner suggests, but rather to provide a substrate for the user of the device to press the bulb walls against to maintain a consistent feel (a compression goal) and to reduce the tendency for the user to randomly squeeze the bulb during the blood pressure simulation (see paragraph 0013). As such, the combined teachings of Baldwin, Morris and Frazier would not be looked to by a skilled artisan to solve the problem solved by the Applicant in this claim. The combination of the references would also render Frazier unsatisfactory for its intended use since the bulb in Frazier is not intended to be compressed by a human hand and, in fact, is not possible to do so in its intended use inside the vascular system of a human. The Applicant submits that the references must be considered as what they teach as a whole and not simply as a tool box for which to build the Applicant's invention. Also, since Claim 43 has all of the limitations of the claim on which it depends and the combination of Baldwin, Morris and Frazier do not teach every element of the claim 43, the Applicant submits, for this reason and those listed above, that Claim 43 is in condition for allowance and requests that the rejection be withdrawn and the claim allowed.

Summary

The Applicant has traversed and/or amended all of the independent claims active in the application and has redrafted many of the independent claims to include more structural limitations as suggested by the Examiner. The Applicant believes all claims are now in condition for allowance. Allowance is hereby respectfully requested. Further, the Applicant believes all dependent claims are in condition for allowance for at least the reason that they contain all limitations of their respective independent claims. Allowance is hereby requested. The Applicant thanks the Examiners for helpful suggestions during the June 26, 2007 interview at the USTPO.

Respectfully Submitted,

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